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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/807,500	02/27/1997	MARC ZEICHER	236007	5090

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EXAMINER
MCGARRY, SEAN

ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 01/11/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 08/807,500	Applicant(s) ZEICHER, MARC	
	Examin r Sean R McGarry	Art Unit 1635	

-- The MAILING DATE of this c mmunication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *17 September 2001* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *3-16,21,22 and 28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3-16, 21, 22, 28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. *08/448,590* .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/17/01 has been entered.

Claims 3-7, 9-12, 14-16, 21, and 22 are rejected under 35 U.S.C. 102(e) as being anticipated by Maxwell et al [US Patent No. 5,585,254]. Applicants arguments are addressed below.

Maxwell et al disclose autonomous Parvoviral gene delivery vehicles and expression vectors. The autonomous vectors include LuIII, MVMi, MVMp, and H1, for example. These vectors are disclosed to express compounds such as antisense RNA, ribozymes, RNA-based drugs, and cytotoxic proteins. It is disclosed that 90 percent of an autonomous parvovirus can be modified tp produce a desired heterologous vector and NS and VP gene can *optionally* be kept in a vector for desired characteristics. It is disclosed that any cis acting nucleic acid sequence from which polymerase can be used to initiate transcription and "response element can be included in the vector. It is disclosed that control elements and coding regions can be combined in a variety of

ways (see column 10, last full paragraph, for example). It is further disclosed that a "cell-selective response element can be include and include, for example, elastase I enhances, and HIV response elements such as TAR. It is also disclosed that virus particles can be produced that selectively target desired cell types (see column 18, for example).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 8, 13, 21, and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Maxwell et al [US Patent 5,585,254]. Applicants arguments are addressed below.

The instant invention is drawn to a parvoviral vectors that include; 1) an enhancer nucleotide sequence specific for CMV and includes a ribozyme directed to CMV, 2) an LTR sequence of HIV that lacks the enhancer NF-Kappa B and/or NRE, 3) a sequence encoding interferon- , interferon- , or PAF-4. 4) the specific promoters/enhances recited in claim 21.

Maxwell et al have taught autonomous Parvoviral gene delivery vehicles and expression vectors. The autonomous vectors include LuIII, MVMi, MVMp, and H1, for example. These vectors express compounds such as antisense RNA, ribozymes, RNA-based drugs, and cytotoxic proteins. It has been taught that 90 percent of an

autonomous parvovirus can be modified tp produce a desired heterologous vector and NS and VP gene can *optionally* be kept in a vector for desired characteristics. It has been taught that any cis acting nucleic acid sequence from which polymerase can be used to initiate transcription and "response element" can be included in the vector. It has been taught that control elements and coding regions can be combined in a variety of ways (see column 10, last full paragraph, for example). Further it has been taught that a "cell-selective response element" can be include and include, for example, elastase I enhancers, and HIV response elements such as TAR. It is also disclosed that virus particles can be produced that selectively target desired cell types (see column 18, for example). Maxwell et al have not specifically taught the specific limitations listed above. However, the specific limitations recited in the instantly rejected claims do not define the instant invention over the prior art. Maxwell et al have taught the general concepts in the construction of parvoviral vectors where the specific limitations are embraced within those teachings. Maxwell have provided several examples for specific embodiments of expression products such as antisense RNA, ribozymes, RNA-based drugs, and cytotoxic proteins and further has taught that control elements and coding regions can be combined in a variety of ways where promoters are suggested and exemplified. The instant limitations would be a matter of routine choice in the choosing of specific promoters, enhancers and desired expression products. The limitations instantly recited are members of the promoter, enhancers and expression products that could have been used in the parvoviral vectors described by Maxwell et al, where the instant limitations represent known promoters, enhancers, expression products and "response elements" that were routinely used in the art at the time of the instant invention. The instant specification does not indicate any unexpected results with the use of the specific element recited in the instant claims, for example. There would have

been an expectation of their successful application since Maxwell et al have described correlative limitations in their parvoviral vectors.

The invention as a whole would therefore have been *prima facie* obvious to one of ordinary skill in that art at the time the invention was made.

Applicant's arguments filed 9/17/01 have been fully considered but they are not persuasive. Applicant cannot rely upon the foreign priority papers to overcome the above rejections under 35 U.S.C. 102(e) and 35 U.S.C. 103(a) because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth below. Applicant is directed to pages 47 and 50, for example, where there are nucleotide sequences disclosed that do not have corresponding sequence identifiers. **Applicant is required to comply with the requirements of 37 CFR 1.821 through 1.825 for a response to the instant Official Action to be considered complete.**

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean R McGarry whose telephone number is (703)305-7028. The examiner can normally be reached on M-Th (6:00-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on (703) 308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are (703)

308-4242 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

SRM
January 9, 2002

SEAN McGARRY
PRIMARY EXAMINER